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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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MEMORANDUM

DATE:

SUBJECT: PP#1F2579. Trifluralin in or on flax. Evaluation of analytical methodology and residue data.

EPA Registration No. 1471-35-AD. Treflan(R) EC. Amended registration request to permit use for weed control in flax.

EPA Registration No. 1471-59-AB. Treflan(R) 5G. Amended registration request to permit use for weed control in flax.

EPA Registration No. 1471-116. Treflan(R) MTF. Amended registration request to permit use for weed control in flax.

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THRU: Charles Trichilo, Chief
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TO: Product Manager, Team 23
(Richard Mountfort),
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and Toxicology Branch
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Elanco Products Co. proposes the establishment of a negligible residue tolerance of 0.05 ppm for the herbicide trifluralin in or on flax.

The petitioner also proposes the amended registration of three trifluralin formulations (listed above) to permit their use for weed control in flax.

Tolerances are presently established (40 CFR 180.207; 21 CFR 193.440) for trifluralin residues in or on a variety of r.a.c.'s at levels ranging between 0.05 ppm and 2 ppm. These include 0.05(N) ppm tolerances in or on the oilseed crops, cottonseed, safflower seed, and sunflower seed.

A tolerance petition proposing a negligible residue tolerance of 0.05 ppm for trifluralin residues in or on the oilseed crop rape seed and straw is apparently still co-pending (PP#OE2394).

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Flax is also an oilseed crop. Flaxseed is also known by the designation "linseed."

Conclusions

1. The nature of the residue in plants and animals is adequately delineated. The residue of concern is trifluralin per se.

2. Adequate analytical methodology is available to enforce the proposed tolerance(s).

3a. The proposed tolerance (0.05 ppm) is adequate to cover residues, if any, of trifluralin which may arise in flaxseed (or its by-products) as a result of the proposed use. If/when this tolerance is established, it should be in terms of "flaxseed", rather than "flax" as the petitioner proposes.

3b. A tolerance proposal is needed for flaxseed straw. Based on translation of data from rapeseed straw (PP#OE2394), we consider 0.05 ppm would be an appropriate level. A revised Section F is needed.

4. The proposed amended registrations (1471-35-AD; 1471-59-AB; 1471-116) to permit use of the Treflan EC, 5G, and MTF formulations, respectively, for weed control in flax are supportable.

5. The proposed use will constitute a 40 CFR 180.6(a)(3) situation with respect to the likelihood of secondary residues arising in meat, milk, poultry, or eggs.

6. An International Residue Limit (IRL) Status sheet is attached. There are no foreign "tolerances" for trifluralin on flax.

7. Low levels (<1 ppm) of nitrosamines impurities are in technical trifluralin, with proportionately less in its formulated products. This level of nitrosamines impurities has not been precluding the establishment of trifluralin tolerances.

Recommendations

Contingent upon receipt of a suitably revised Section F (see Conclusion 3b), and TOX and EFB (crop rotation) considerations permitting, we could recommend in favor of the following proposed trifluralin tolerances:

Flaxseed	0.05 ppm
FLaxseed Straw	0.05 ppm

and the amended registrations (1471-35-AD ; 1471-59-AB; and, 1471-116) to permit use of the Treflan EC, 5G, and MTF formulations, respectively, for weed control in flax, as the petitioner has proposed.

Product Manager, note Conclusion 3a re "flaxseed."

Detailed Considerations

Manufacture and Formulation

The manufacturing process of technical trifluralin is available in RD files. N-nitroso-dipropylamine (NDPA) is present as an impurity. Total nitrosamines in commercially produced technical trifluralin are reportedly <1 ppm, with proportionately less in the formulated products. (See Progress Report on the Reduction of the Nitrosamine Impurity in Trifluralin Production, 12/11/78, filed with the correspondence, PP#9F2172.) This level of nitrosamines impurities has not been precluding the establishment of trifluralin tolerances. Other (non-nitrosamine) impurities are not expected to cause a residue problem.

Three formulations are proposed for use: Treflan EC (EPA Registration No. 1471-35-AD), Treflan 5G (EPA Registration No. 1471-59-AB), and Treflan MTF (EPA Registration No. 1471-116).

Treflan EC is a 4 lbs ai/gal. emulsifiable concentrate formulation containing 44.5% a.i. (trifluralin) and 55.5% inert ingredients. Treflan 5G is a granular formulation containing 5% trifluralin as ai and 95% inert ingredients. Treflan MTF Is a 4 lbs a.i./gal. Multiple Temperature Liquid Formulation containing 41.2% a.i. (trifluralin) and 58.8% inert ingredients.

All the inert ingredients in these three registered formulations are cleared for use under 40 CFR 180.1001.

Proposed Use

Treflan EC, 5G, and MTF formulations are recommended for use for weed control as a fall-applied soil-incorporated treatment prior to seeding flax the following spring.

Apply the EC, 5G, or MTF formulation at a broadcast rate of 0.5-1.0 lb ai/A, depending on soil texture.

Do not apply Treflan granules (i.e., 5G) by aerial application.

Various crop rotation restrictions apply which vary with geographic regions. (See individual labels for specifics.)

Nature of the Residue

The metabolic fate of trifluralin in plants and animals has been extensively discussed in previous reviews (see memos by T. Woodward, PP#7G0533, 10/31/66; R. Arnold and J. Wolff, PP#7F0555, 5/24/67).

Trifluralin is readily absorbed and translocated in plants. Radiotracer studies ($^{14}CF_3$) on carrots, peanuts, soybeans, sweet potatoes, and cotton indicate the major degradation routes include a stepwise dealkylation of the aniline group and a partial or complete reduction of the nitro groups. Carboxylation of the trifluoromethyl group has also been demonstrated to a lesser degree.

There are no new metabolism data in the present proposal to elucidate the metabolic fate of trifluralin in flax; however, we believe that the degradation behavior demonstrated in the above plant studies can be extended to the proposed use.

Metabolism studies with radiolabeled trifluralin in dogs and rats indicate a complete excretion of the radioactivity takes place within three days following administration of a single oral dose. The degradation products were also dealkylated and reduced metabolites of trifluralin, and similar to those found in the plant studies.

We conclude that the nature of the residue in plants and animals is adequately delineated. The residue of concern is trifluralin per se.

Analytical Method

Trifluralin residue data on flaxseed were obtained with Elanco Procedure 5801616, "Determination of Trifluralin in Agricultural Crops and Soil." This procedure is essentially the same as Method II in PAM Vol. II except that an aliquot of the initial crop extract, rather than the entire extract, is taken for clean-up and gas chromatographic analysis. The basic procedure underwent a successful method trial in re PP#7F0555.

Trifluralin is extracted from flaxseed with methanol. An aliquot of the extract is purified by liquid-liquid extraction with methylene chloride and by Florisil column chromatography. The final measurement is made by electron-capture gas-liquid chromatography. Method sensitivity is 0.01 ppm.

For crops containing interfering BHC, Ethion and/or Zineb residues, a thin-layer chromatography method is available for initial clean-up.

Control samples of flaxseed fortified with trifluralin at 0.04 ppm and assayed with each run of experimental samples exhibited recoveries ranging 55-88% of the amount added. "Blank" values were reported as either NDR (no detectable residue; GLC response equivalent to <0.01 ppm trifluralin) or <0.04 ppm (samples which exhibited a GLC response >0.01 ppm but <0.04 ppm were all reported as <0.04 ppm).

We conclude that adequate analytical methodology is available to enforce the proposed tolerance.

Residue Data

Seven field experiments with flaxseed, representing two different varieties, were conducted in crop years 1977-79 in the states of MN, ND, and SD (the major flax-growing states).

The trifluralin formulations, Treflan 4EC or 5G, were fall-applied as a preplant soil incorporated (PPI) application for weed control at rates of 0.5, 0.75, or 1.0 lb ai/A (1X rate), then flaxseed planted the following spring.

[Note: Even though the MTF formulation and (possibly) aerial application were not utilized in the field trials, we are not questioning this because of the timing of the proposed use (several months PPI).]

Samples of mature flaxseed were collected at harvest and analyzed for trifluralin residues. The flaxseed from two of these experiments showed no detectable residue (NDR), while trifluralin residues of less than 0.04 ppm were found in both treated and untreated (control) samples in the other five experiments. The samples from these studies were assayed using a variety of GC columns which indicates that the response on the chromatogram is due to trifluralin.

Since these occasional low level residues were encountered in both treated and control samples, the petitioner theorizes the cause to be contamination (by contact with treated soil) during the harvesting process.

Residue data which is available on other oilseed crops (rapeseed, PP#OE2394; cottonseed and safflower seed, PP#8F0664; and, sunflower seed, PP#8F0679) from treatment of soils with Treflan at rates in excess of those proposed in this petition indicate no detectable residues (<0.01 ppm) were ever encountered in those oilseeds.

We conclude that the proposed tolerance (0.05 ppm) is adequate to cover residues, if any, of trifluralin which may arise in flaxseed as a result of the proposed use.

[Note: The proposed tolerance if/when established should be for "flaxseed," not "flax."]

By translation of the rationales, data, etc. from these other oilseed petitions, we likewise conclude that no residues of trifluralin in excess of those (if any) in the seed are to be expected in the flaxseed by-product hulls, meal, and oil.

Additionally, residue data in the recent petition on rapeseed (PP#OE2394) provides assurance that residues in excess of 0.05 ppm are not to be expected in straw either. In fact, NDR (<0.01 ppm) were encountered, even at exaggerated rates.

By translation of that data, we request the petitioner propose a 0.05 ppm tolerance for flaxseed straw, a minor livestock feed item.

Flax plants are not grown for forage. Green, immature flaxseed may contain poisonous amounts of prussic acid and mature plants are harvested for their economically profitable oilseed rather than foraged. Thus, neither a tolerance proposal nor feeding/grazing restriction for the forage is needed.

In conjunction with our favorable recommendation for the proposed tolerance (0.05 ppm) on flaxseed (and flaxseed straw), we also recommend for the amended registrations (1471-35-AD; 1471-59-AB; and 1471-116) to permit use of the Treflan EC, 5G, and MTF formulations, respectively, for weed control in flax.

Residues in Meat, Milk, Poultry, or Eggs

The feed items in this petition are flaxseed per se, its hulls, meal, and straw. [The oil (aka linseed oil) is not used for feed (or food) in the USA (industrial use only).]

We classify their feed use within 40 CFR 180.6(a)(3) on the basis of the feeding study data available in our files (see PP#7F0565), and other considerations, with respect to the likelihood of secondary residues arising in meat, milk, poultry, or eggs as a result of the proposed use.

Other Considerations

An International Residue Limit (IRL) Status sheet is attached to this review. According to it, there is no established IRL or Codex Proposal (step 6 or above) for trifluralin residues in or on flax.

Attachment